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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/706,542 | 11/12/2003 | Linda S. Powers | 13368.0001 (DIV. II) | 6889 |

7590 12/16/2004
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EXAMINER

LUCAS, ZACHARIAH

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1648

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/706,542

Applicant(s)

POWERS ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Renumbered claim set.

DETAILED ACTION

1. Currently, claims 1-13 are pending in this application.
2. **Note RE: Preliminary Amendment.** A Preliminary Amendment was filed in this application on November 12, 2003. However, this amendment does not conform with the requirements of 37 CFR 1.121 in that the amendment does not present a complete listing of the claims (both the original claims and the amended claims) and marking the claims with the appropriate parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered). In view of this, the amendment has not been entered into the application.

While the proposed amendment would not affect the restriction requirement set forth below, if the Applicant desires that the amendments be considered with respect to the invention elected in response to this action, the Applicant is required to submit an amendment making the appropriate changes in conformance with the requirements of 37 CFR 1.1.21.

3. The numbering of the originally filed claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 38-50 have been renumbered, respectively, as claims 1-13.

Election/Restrictions

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4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-13, drawn to methods of taxonomic identification of a bacteria, classified in class 435, subclass 7.32.
 - II. Claims 1-13, drawn to methods of taxonomic identification of a virus, classified in class 435, subclass 5.
 - III. Claims 1-13, drawn to methods of taxonomic identification of a proteinaceous toxin classified in class 435, subclass 7.1.
 - IV. Claims 1-13, drawn to methods of taxonomic identification of a rickettsiae, classified in class 435, subclass 7.22.
 - V. Claims 1-13, drawn to methods of taxonomic identification of a protozoa, classified in class 435, subclass 7.22.
 - VI. Claims 1-13, drawn to methods of taxonomic identification of a fungi, classified in class 435, subclass 7.31.
 - VII. Claims 1-13, drawn to methods of taxonomic identification of a cytosolic protein, classified in class 435, subclass 7.1.

For each of Groups I-VII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-VII, and one of inventions (i)-(v).

Subgroups i-v represent the elected invention, wherein the ligand is:

- (i) a heme compound;
- (ii) a siderophore;
- (iii) a polysaccharide;
- (iv) a peptide specific for an outer membrane protein; and
- (v) a peptide specific for a conjugated lipid.

The inventions are distinct, each from the other because of the following reasons:

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5. The inventions of subgroups (i)-(v) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are disclosed as usable together, and each of the inventions has a different mode of operation from the other inventions because they use a ligand that binds to a different target analyte, or is a different compound, from the ligands used in the other claimed methods. The inventions are therefore distinct inventions one from another.

6. The inventions of Groups I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relates to a method of detecting a different biological analyte. Thus, each of the claimed methods if performing a different function. The inventions are therefore distinct.

Species Election

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

For the elected invention from Groups I-VII above, the Applicant is additionally required to elect a species of the claimed method selected from the following:

(a) the claimed method wherein the separation of the bound ligand from the excess ligand is through chromatography, or

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(b) the claimed method wherein the separation of the bound ligand from the excess ligand is through magnetic separation with the ligand being tethered to the magnetic particle.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Examiner Notes

8. In claim 2, the Applicant has recited a list of alternative embodiments for the claimed invention. This list identifies the different alternative embodiments with a letter. However, these letters are presented in a format continuing the letters used to identify the steps of claim 1. However, the letters in claim 2 are not identifying additional steps to the method of claim 1, but are identifying the analyte detected by the method comprising those steps. It is therefore suggested that the Applicant amend the claims to refer to the various analytes either alone (i.e. not using a separate letter or number identifier), or with an alternative for of identifier from the letters used in claim 1.

Conclusion

9. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

10. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn.

Claim 1 is considered as a linking claim among the various inventions.


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11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 12/13/04
SUPERVISORY PATENT EXAMINER
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